

REMARKS**I. INTRODUCTION**

In response to the Office Action dated December 15, 2004, withdrawn claims 1-22 and 59-82 have been cancelled, claims 23, 30, 35, 41, 48 and 53 have been amended and claims 83-139 have been added. Claims 23-58 and 83-139 remain in the application. Entry of these amendments, and re-consideration of the application, as amended, is requested.

II. CLAIM AMENDMENTS

Applicants' attorney has made amendments to the pending claims as indicated above. Independent claim 23 has been amended to recite a system for delivering medication, comprising: an infusion pump; and a control system for controlling medication delivery by the infusion pump; wherein the control system includes a plurality of medication delivery profiles and a plurality of suspend functions capable of separately suspending the plurality of medication delivery profiles; and wherein the system for delivering medication is compact and adapted to be carried by a user. Independent method claim 41 has also been amended in an analogous manner. These amendments are fully supported by the specification and introduce no new matter (see, e.g. paragraph [4] of the specification). The term "compact" in these amended claims is used according to its accepted meaning of "occupying a small volume by reason of efficient use of space" (see, e.g. the definition of this term on page 233 of Merriam-Webster's Collegiate Dictionary, 10th Ed., a copy of which is attached as Exhibit A).

Applicants' attorney has added new claims as indicated above which recite further elements that are common in embodiments of the invention where the system for delivering medication is compact and adapted to be carried by a user. For example, certain new claims recite systems including a reservoir for containing the medication, a drive mechanism to deliver the medication from the reservoir etc. (e.g. claim 83). Such embodiments of the invention are discussed throughout the specification and introduce no new matter (see, e.g. paragraphs [24]-[25] of the specification). Certain new claims also recite systems for example where the control system controls medication delivery from the reservoir in accordance with the plurality of medication delivery profiles, such that two or more of the plurality of medication delivery profiles can be used to deliver medication at the same time, and wherein at least one of the plurality of suspend functions may be used independently

of at least one of the other of the plurality of suspend functions, such that medication delivery continues from the reservoir in accordance with at least one of the plurality of medication delivery profiles (see, e.g. claim 85). Such embodiments of the invention are discussed throughout the specification and introduce no new matter (see, e.g. paragraphs [69]-[70] of the specification).

In addition minor amendments were made to certain claims in order more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. These amendments are fully supported by the specification and introduce no new matter.

III. PRIOR ART REJECTIONS

On page (3) of the Office Action, claims 23 and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by Orkin et al., U.S. Patent No. 5,207,642 (Orkin). On page (4) of the Office Action, claims 24-40 and 42-58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Orkin and/or Kerns et al., U.S. Patent No. 4,756,706 (Kerns) in view of Lebel et al., U.S. Patent No. 6,562,001 (Lebel1), Lebel et al., U.S. Patent No. 6,810,290 (Lebel2) and further in view of Rodler, U.S. Patent No. 4,457,751 (Rodler).

Applicants respectfully traverse these rejections.

A. The Claimed Invention

In response to the outstanding office action, the pending claims have been amended to clearly recite embodiments of the invention where the system for delivering medication is compact and adapted to be carried by a user. In particular, Applicants' specification teaches that embodiments of the invention are directed to infusion devices such as those that deliver insulin to a user who suffers from diabetes. The specification teaches that those types of infusion devices are typically compact as well as water resistant, and may thus be adapted to be carried by the user, for example, by means of a belt clip. As a result, medication can be delivered to the user with precision and in an automated manner, without significant restriction on the user's mobility or lifestyle, including the ability to participate in water sports. See, e.g. paragraph [4] of the specification.

In addition, in response to the outstanding office action new claims are introduced which recite further elements that are common in embodiments of the invention where the system for delivering medication is compact and adapted to be carried by a user (e.g. claim 83).

B. Rejection under 35 U.S.C. §102(b)

On page (3) of the Office Action, claims 23 and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by Orkin et al., U.S. Patent No. 5,207,642 (Orkin).

Applicants respectfully traverse this rejection because Orkin fails to teach systems and/or methods for delivering medication to a user where the system for delivering medication is compact and adapted to be carried by a user. Instead, Orkin teaches a large multi-fluid delivery system in the form of a mobile hospital cart having a framework designed to accommodate hanging IV bags filled with fluid medications. These hanging medication bags are coupled to tubes that are then controlled by electrically actuated clamps or tubing occluders designed to modulate fluid flow. In order to allow this type of multi-fluid delivery system to be mobile, the cart, the IV bags, the tubes and occluders etc. are mounted on a plurality of casters which allow this system to be pushed around a hospital room (see, e.g. column 9, lines 30-58 as well as FIG. 2 and FIG. 18).

Because Orkin fails to teach a system for delivering medication that is compact and adapted to be carried by a user, this reference cannot anticipate the claimed invention. In particular, as noted for example in M.P.E.P. 2131, a claim is anticipated only if each and every element as set forth in the claim is found in a single art reference. As Orkin fails to teach a compact medication delivery system, much less one adapted to be carried by a user, this disclosure cannot anticipate the claimed subject matter. For this reason, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b).

C. Rejections under 35 U.S.C. §103(a)

On page (4) of the Office Action, claims 24-40 and 42-58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Orkin and/or Kerns et al., U.S. Patent No. 4,756,706 (Kerns) in view of Lebel et al., U.S. Patent No. 6,562,001 (Lebel1), Lebel et al., U.S. Patent No. 6,810,290 (Lebel2) and further in view of Rodler, U.S. Patent No. 4,457,751 (Rodler).

Applicants respectfully traverse the rejection in view of Orkin because this reference fails to teach or suggest systems and/or methods for delivering medication to a user where the system for

delivering medication is compact and adapted to be carried by a user. As noted above, Orkin teaches a closed multi-fluid delivery system in the form of a mobile hospital cart designed to accommodate hanging IV bags filled with fluid medications. Orkin further teaches that these systems are designed to exhibit a number of advantageous properties. Specifically, at column 5, lines 65-69 Orkin teaches that systems having this design allow the combined fluid-flow output to be delivered by means of the force of gravity. At column 7, lines 42-44, Orkin teaches that with systems having this design the desired schedule of fluids to be delivered to a patient can range from 20 ml/hr to 100 ml/hr of fluid.

A comparison of the system disclosed in Orkin and the claimed invention shows that substantial modifications are required to reorganize the Orkin hanging IV cart system in a manner that would generate a system for delivering medication that is compact and adapted to be carried by a user (if this is even possible). However, Orkin fails to provide a teaching on how this would be accomplished or even a motivation to modify their system in this manner. Consequently, this reference cannot be used to render the claimed invention obvious. In particular, obviousness can only be established by combining, modifying the teaching of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. M.P.E.P. 2143.01, *In re Fine*, 5 USPQ 2d 1596 (Fed. Cir. 1988).

In addition, as noted above, the Orkin reference teaches that their multi-fluid delivery system exhibits a number of advantageous functions such as the ability to use gravity to deliver fluid volumes that range from 20 ml/hr to 100 ml/hr. In this context, any modifications to the Orkin system that attempted to make it compact and adapted to be carried by a user would not facilitate and would instead compromise the operability of these functions. Such modifications would therefore render the Orkin system unsatisfactory for its intended purpose. As noted in M.P.E.P. 2145(D), any proposed modification cannot render the prior art unsatisfactory for its intended purpose. Consequently, the Orkin reference cannot be used in a rejection under 35 U.S.C. 103(a). For this reason, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) in view of the Orkin disclosure.

Applicants respectfully traverse the rejection in view of Kerns because, like Orkin, this reference fails to teach or suggest systems and/or methods for delivering medication to a user where

the system for delivering medication is compact and adapted to be carried by a user. In particular, like Orkin, Kerns teaches a large system which utilizes hanging IV bags filled with fluid medications (see, e.g. column 2, lines 45-48 and FIG. 1). In addition, Kerns explicitly teaches that the invention is a modular system in which the hanging IV bags, pumps and monitoring modules can be selectively attached, both physically and electrically, to a central management unit. This central management unit then controls the internal setup of all modules attached to it, and receives and displays information from them. Each of the modules is capable of being detached from the central management unit, and while so detached is capable of operating independently for an extended period of time. See, e.g. the Kerns specification at column 1, lines 40-50.

A comparison of the system disclosed in Kerns and the claimed invention shows that substantial modifications would be required to reorganize Kerns' modular hanging IV bag system in a manner that would generate a system for delivering medication that is compact and adapted to be carried by a user (if this is even possible). However, like Orkin, Kerns fails to provide a teaching on how this would be accomplished or a even motivation to modify their system in this manner. Consequently, this reference cannot be used to render the claimed invention obvious. In particular, obviousness can only be established by combining, modifying the teaching of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. M.P.E.P. 2143.01, *In re Fine*, 5 USPQ 2d 1596 (Fed. Cir. 1988).

In addition, the Kerns disclosure teaches a system designed so that a plurality of infusion pump modules are detachably connected to a portable central management unit. This type of detachable modular system (i.e. having multiple detachable components that are linked by a central management unit) teaches away from the compact system recited in the amended claims. Consequently, when the systems disclosed in Kerns are examined in the context of the whole disclosure (as required by M.P.E.P. 2141, see e.g. *Hodosh v. Block Drug Co., Inc.*, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986)), it is clear that this disclosure cannot teach or suggest the invention recited in pending claims 24 and 42. Specifically, because a reference that teaches away from a claimed invention cannot be used to render that invention obvious, the Kerns reference cannot be used in a rejection under 35 U.S.C. 103(a). See, e.g. M.P.E.P. 2145(D)(2), *In re Grasselli*, 218 USPQ 769, 779 (Fed. Cir. 1983). For this reason, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) in view of the Kerns disclosure.

As noted above, the Orkin and Kerns disclosures fail to teach or suggest the claimed invention. In addition, a review of the Lebel1, Lebel2, and Rodler references shows that the disclosures in these patents fail to overcome the deficiencies in the Orkin and Kerns disclosures (which is understandable as they are cited by the Examiner merely in view of the basal, square wave and dual wave profiles recited in the pending claims). Consequently, a combination of the disclosures in the Orkin and/or Kerns in view of Lebel1, Lebel2, and Rodler cannot be used to generate the claimed invention. For this reason, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. §103(a).

In addition, the various elements of Applicants' claimed invention together provide operational advantages over the systems disclosed in Orkin, Kerns, Lebel1, Lebel2, and Rodler. In addition, Applicants' invention solves problems not recognized by Orkin, Kerns, Lebel1, Lebel2, and Rodler. Thus, Applicants submit that independent claims 23 and 41 are allowable over Orkin, Kerns, Lebel1, Lebel2, and Rodler. Further, dependent claims 24-40 and 42-58 are submitted to be allowable over Orkin, Kerns, Lebel1, Lebel2, and Rodler in the same manner, because they are dependent on independent claims 23 and 41, respectively, and because they contain all the limitations of the independent claims. Finally, dependent claims 24-40 and 42-58 recite additional novel elements not shown by Orkin, Kerns, Lebel1, Lebel2, and Rodler.

IV. CONCLUSION

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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